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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/526,579	01/09/2006	Jonathan W. Francis	MO765.70044US01	3818

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EXAMINER	
MACFARLANE, STACEY NEE	
ART UNIT	PAPER NUMBER
1649	
MAIL DATE	DELIVERY MODE
03/13/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/526,579	FRANCIS ET AL.	
	Examiner	Art Unit	
	STACEY MACFARLANE	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,13,19,34,43-45,55,61,76,85-87,97,103,106 and 119* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-3, 13, 19, 34, 43-45, 55, 61, 76, 85-87, 97, 103, 106 and 119* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-3, 13, 19, 34, 43-45, 55, 61, 76, 85-87, 97, 103, 106 and 119, in so far as they are drawn to a method comprising administering a hybrid protein comprising a therapeutic molecule wherein the therapeutic molecule is a protein.

Group II, claim(s) 1-3, 13, 19, 34, 43-45, 55, 61, 76, 85-87, 97, 103, 106 and 119, in so far as they are drawn to a method for administering a therapeutic molecule wherein the therapeutic molecule is a gene therapy molecule: nucleic acid molecule, oligonucleotide, RNA molecule, virus, plasmid, cosmid or bacmid.

Group III, claim(s) 1-3, 13, 19, 34, 43-45, 55, 61, 76, 85-87, 97, 103, 106 and 119, in so far as they are drawn to a method for administering a therapeutic molecule wherein the therapeutic molecule is an antibody.

Group IV, claim(s) 1-3, 13, 19, 34, 43-45, 55, 61, 76, 85-87, 97, 103, 106 and 119, in so far as they are drawn to a method for administering a therapeutic molecule wherein the therapeutic molecule is a lipid.

Group V, claim(s) 1-3, 13, 19, 34, 43-45, 55, 61, 76, 85-87, 97, 103, 106 and 119, in so far as they are drawn to a method for administering a therapeutic molecule wherein the therapeutic molecule is a polysaccharide.

2. The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: proteins, nucleic acids, antibodies, lipids and polysaccharides are each structurally and functionally

distinct products. The single general inventive concept that permeates the groups of molecules is that they are part of a hybrid protein with tetanus toxin fragment C that for targeting to the cerebrospinal fluid or directly into the brain or spinal cord parenchyma. The expression "special technical feature" is defined in Rule 13.2 as meaning those technical features that define a contribution which each of the inventions makes over the prior art. Whether a particular feature makes a contribution over the prior art, is considered with respect to novelty and inventive step. In the instant application, hybrid proteins with tetanus toxin fragment C, and their ability to target brain or spinal cord parenchyma, do not make a contribution over the prior art. The following reference discloses the special technical feature of a superoxide dismutase-tetanus toxin fragment C hybrid protein for targeted delivery to the central nervous system (Francis et al. Journal of Biological Chemistry, 270:15434-15442, 1995). Thus, the prior art recites the common technical feature of Groups I-V, thus, there is no special technical feature over the prior art and the application lacks Unity of Invention under PCT Rule 13.1. Furthermore, the methods comprising administration of structurally and functionally distinct molecules constitute patentably distinct inventions. The instant specification does not disclose that these methods would be used together. The methods of Groups I-V are all unrelated as they comprise distinct methodology and utilize different products, which demonstrates that each method has a different mode of operation. Each invention performs this function using structurally and functionally divergent material. Moreover, the methodology and materials necessary for treatment of diseases differ significantly for each of the materials as claimed.

Species Election

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

The structurally distinct proteins as recited in Claims 3, 45, and 87.

The etiologically, pathologically, and symptomologically distinct diseases from those recited in Claim 106.

4. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The growth factors of Claims 3, 45, and 87 are not so linked that they form a general inventive concept under PCT Rule 13.1, each is structurally and functionally distinct and do not have a unifying characteristic that links them as a group over the prior art. Likewise, the diseases listed in Claim 106 are etiologically, pathologically, and symptomologically distinct and are not so linked as to form a general inventive concept that distinguishes them as a group apart from other diseases within the prior art.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claim(s) are generic: Claims 1, 43, and 85 are generic.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected invention.**

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to STACEY MACFARLANE whose telephone number is (571)270-3057. The examiner can normally be reached on M,W and ALT. F 6 am to 3 pm, T & R 5:30 am - 4 pm..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Stacey MacFarlane
Examiner
Art Unit 1649

/SNM/

/Olga N. Chernyshev, Ph.D./
Primary Examiner, Art Unit 1649